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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,231	03/26/2004	Gregory Alan Lazar	A-71386-8	1316

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EXAMINER

CROWDER, CHUN

ART UNIT PAPER NUMBER

1644

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/822,231

Applicant(s)

LAZAR ET AL.

Examiner

Chun Crowder

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 8-12, 14-16, 18-20 and 37-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 13, 17, 21-36, 44, and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendments, filed 08/15/2006, are acknowledged.

Claims 1, 21, and 22 have been amended.

Claims 44 and 45 have been added.

Claims 1-45 are pending.

Claims 8-12, 14-16, 18-20, and 37-42 have been withdrawn from further consideration under 37 C.F.R. 1.142(b) as being drawn to nonelected inventions.

Claims 1-7, 13, 17, 21-36, 44, and 45 are under consideration in the instant application as they ready on the originally elected invention of Group I and species of IgG1, position 332E, and non-engineered glycoforms.

2. This Office Action will be in response to applicant's arguments, filed 08/15/2006.

The rejections of record can be found in the previous Office Action, mailed 02/15/2006.

The text of those Sections of Title 35 U.S.C. not included in this Action can be found in a prior Action.

3. Applicant's IDS, filed 05/15/2006, is acknowledged and has been considered.

4. Applicant's correction in claim numbering is acknowledged and has been entered.

5. Applicant's arguments regarding priority issues are acknowledged. Applicant has not provided support for the claimed limitations of "position 332" of the Fc region in the provisional application USSN 60/414,433; thus the instant claims are not accorded the priority date of 09/27/2002.

In response to applicant's assertion that the present application was granted priority to provisional application USSNs 60/384,197 and 60/360,843, it is noted that the petition to an unintentionally delayed claim under 35 U.S.C. 119(e) to USSNs 60/384,197 and 60/360,843 was granted on 04/12/2006. The granting of the petition to accept the delayed benefit claim to the prior-filed applications should not be constructed as meaning that the application is entitled to the benefit of the filing date of the prior-filed applications.

In this case, the provisional applications USSNs 60/384,197 and 60/360,843, upon which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for the instant claims. Specifically, insufficient support was identified for the limitation of "position 332" of the Fc region. Therefore, the instant claims have not been accorded the priority of the USSNs 60/384,197 (03/01/2002) and 60/360,843 (05/29/2002). Consequently, the claims have been accorded the priority of the USSNs: 10/672,280, 10/379,392, 60/477,839, 60/467,606, and 60/442,301 with earliest priority date of 01/23/2003.

6. Claims 13, 17 and 32 are objected to because of the following informalities:

A) Claims 13 and 17 are dependent on any of claims 1-12. However, claims 8-12 are drawn to non-elected invention.

B) Claim 32 is objected to because it is not clear what claim it is dependent upon. For examination purposes, claim 32 is read as dependent on claim 1.

Appropriate correction is required.

7. Claims 1-7, 13, 17, 21-33, and 36 are rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record.

Claims 1-7, 13, 17, 21-33, and 36 recite "Fc variant" as part of the invention.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that the claims have been amended to recite specific substitution positions within the Fc variant; the newly added claims 44 and 45 now recite "antibody" and "Fc fusion". Further, applicant argues that the instant specification has defined the "Fc fusion" as a protein wherein one or more polypeptides are operably linked to Fc; thus, Fc fusion is meant to be synonymous with "immunoadhesin", "Ig fusion", "Ig chimera" and "receptor globulin".

This is not found persuasive for following reasons:

Contrary to applicant's assertion, the specification teaches that a "Fc variant" according to the definition of a variant polypeptide meant an Fc sequence that differs from a parent Fc sequence by at least one amino acid modification, e.g. from about one to about ten amino acid modification, or possess at least 80% homology with a parent polypeptide sequence (see pages 30-31).

Amending the claims to recite the specific amino acid substitution positions does not change the scope of claims, which are drawn to an extensive "Fc variant". There does not appear to be sufficient guidance in the specification as filed as to how the skilled artisan would make and use the claimed "Fc variant". The specification provides insufficient direction or guidance regarding how to make and use "Fc variant" as broadly defined by the claims.

Applicant is once again suggested to amend the claimed Fc variant/polypeptide to antibody and/or Immunoadhesin as disclosed on pages 28-29 of the instant specification to obviate this rejection.

8. Claims 1-7, 13, 17, 21-33, and 36 are rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following *written description* rejection is set forth herein.

Applicant's arguments and the examiner's rebuttal are essentially the same as discussed above in Section 7.

Applicant is once again invited to consider amending the claimed Fc variant/polypeptide to antibody and/or Immunoadhesin as disclosed on pages 28-29 of the instant specification to obviate this rejection.

9. Claims 1-7, 13, 17, 21-36 and newly added claims 44 and 45 are **provisionally rejected on the ground of nonstatutory obviousness-type double patenting** as being unpatentable over claims 1-5, 7, 8, 10-28, 30-41, 43-53, 59, and 61 of copending USSN 10/672,280 for reasons of record.

Applicant requests that the provisionally rejection be held in abeyance until allowable subject matter has been identified in the instant application and USSN 10/672,280.

Given that no terminal disclaimer signed by the assignee and fully complied with 37 CFR 3.73(b) was filed, the provisional rejection on the ground of nonstatutory obviousness-type double patenting is maintained.

10. Claims 1-7, 13, 17 and 21-36 are directed to an invention not patentably distinct from claims 1-5, 7, 8, 10-28, 30-41, 43-53, 59, and 61 of commonly assigned 10/672,280 for the reasons of record.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

11. Upon further consideration as well as applicant's amendments, the previous objection and rejections under **35 U.S.C. 112, second paragraph, first paragraph** regarding "effector function" have been withdrawn.

12. Given that the provisional applications USSNs: 60/360,843 and 60/384,197 to which both the instant application and the prior art Lazar et al. (WO 03/074679) relied on for priority do not have adequate support under 35 U.S.C. 112 for the claimed limitation of the "position 332" of the Fc region, the rejections under **35 U.S.C. 102(e) and 103(a)** have been withdrawn.

13. Amino acid modification at position 332 of the Fc region appears to be free of the prior art.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

15. *Conclusion: No claim is allowed.*

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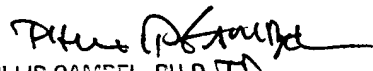
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.

Patent Examiner

November 2, 2006


PHILLIP GANGE, PH.D. JD
PRIMARY EXAMINER
72600
11/6/06